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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/609,298	06/27/2003	Paola LaColla	IDX 1017 US 06171.105078	9201

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KING & SPALDING LLP
1180 PEACHTREE STREET
ATLANTA, GA 30309

EXAMINER	
MCINTOSH III, TRAVISS C	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 08/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/609,298	LACOLLA ET AL.	
	Examiner	Art Unit	
	Traviss C. McIntosh	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,12,17-25 and 43-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,12,17-25 and 43-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 June 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/10/04, 9/16/04,* + 5/15/06
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group XV in the reply filed on 5/15/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Response to Amendment

Claims 1-10, 13-16, and 26-42 have been canceled.

Claims 11, 18, and 22-24 have been amended.

Claims 43-65 have been added.

An action on the merits of claims 11-12, 17-25, and 43-64 is contained herein below.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-12, 17-25, and 43-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claim 1 is drawn to a method of treating a host infected with a *Flaviviridae* virus, comprising administering an effective amount of a compound or a pharmaceutically

acceptable salt thereof wherein the compound has the claimed structure. However, the term, "effective amount" is indefinite where the claim fails to state the function which is to be rendered effective. See ***In re Frederiksen, 102 USPQ 35 (CCPA 1954).*** The claim fails to state what is actually being treated, as such, is seen to be indefinite. It is noted that because a host has a particular viral infection, the claim does not state that that particular viral infection is what is intended to be treated by the instant therapy. Moreover, claim 1 is silent to who the compound is intended to be administered. The claim would be more favorably read as: "a method for the treatment of a *Flaviviridae* virus infection in a host comprising administering to a host infected with a *Flaviviridae* virus infection an effective amount of a compound or a pharmaceutically acceptable salt thereof..."

The term "substantially pure" in claim 21 is a relative term which renders the claim indefinite. The term "substantially pure" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Indicating what is intended by "substantially pure" numerically as in claims 22 or 23, or pointing to the specification where applicants have properly defined "substantially pure", would be seen to obviate the instant rejection.

Claim 54 recites the limitation "wherein R^2 is H" in the first line. There is insufficient antecedent basis for this limitation in the claim. Claim 11, the claim from which this depends, does not afford the variable at the R^2 moiety as being alternatively H, as such, applicants cannot limit claim 11 to something which is outside of it's scope.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11-12, 17-25, and 43-65 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-32 of U.S. Patent No. 6,812,219. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to treating flavivirus infections in a host using 2'-methyl-pyrimidine nucleoside. It is noted that the instant application requires compounds which provide H or phosphate in vivo at the 3' and 5' positions, and the '219 patent comprises H or phosphate at the 3' and 5 positions, however, the '219 patents claims are also drawn to "or prodrugs thereof", and defining moieties in the instant application as leaving groups which provide H or phosphate in vivo is seen to overlap with the prodrugs of the '219 patent. One of skill in the art would find it obvious that these groups are substantially overlapping.

Claims 11-12, 17-25, and 43-65 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of U.S. Patent No. 6,914,054. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to treating flavivirus infections in a host using 2'-methyl-pyrimidine nucleoside. While the '054 patent is drawn to treating HCV, it is known that HCV is a flavivirus, and applicants even limit their methods in the instant application to treating HCV (see claim 12), as such, methods of treating flavivirus and HCV are seen to be obvious over each other. Moreover, it is noted that the instant application requires compounds which provide H or phosphate in vivo at the 3' and 5' positions, and the '054 patent comprises H or phosphate at the 3' and 5 positions, however, the '054 patents claims are also drawn to "or esters thereof", and defining moieties in the instant application as leaving groups which provide H or phosphate in vivo is seen to overlap with the esters of the '219 patent as esters are known to be prodrug moieties (as applicants also claim the leaving groups to be esters). One of skill in the art would find it obvious that these groups are substantially overlapping.

Applicants are also advised that provisional double patenting rejections may also be made over copending applications 11/005,443 and/or 11/005,440. Both of these applications claim overlapping subject matter. Both of the applications are currently abandoned, but petitions have been filed in each of them to revive the applications, as such, if the applications are revived, then double patenting rejections may be required to be made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C. McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Traviss C. McIntosh III
July 22, 2006
Art Unit 1623